UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,060	02/28/2005	Claire Ashman	PG4938	5451

20462 7590 11/21/2007

SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
P. O. BOX 1539
KING OF PRUSSIA, PA 19406-0939

EXAMINER	
KIM, YUNSOO	
ART UNIT	**PAPER NUMBER**
1644	

NOTIFICATION DATE	DELIVERY MODE
11/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/526,060	ASHMAN ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-21,24-32,35,36 and 39-42* is/are pending in the application.

4a) Of the above claim(s) *24-32,35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-21 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments filed on 10/10/07 have been entered.
Claims 1-4, 6-21, 24-32, 35, 36 and 39-42 are pending.

2. Applicant's election with traverse of Group I, Claims 1-4, 6-21 and 39-42 drawn to an immunogenic composition comprising IL-13 and T cell epitope with the elected species of SEQ ID NO:10 (Immunogen I) as an IL-13 element is acknowledged.

The restriction is traversed on the basis of search burden. As indicated in the original restriction requirement mailed 7/17/07, the inventions of Group I -IV were found to have no special technical feature that defined the contribution over the prior art as represented by WO99/51643. Therefore, under PCT Rule 13.1 and 13.2, unity of invention does not exist. As claimed invention lacks the special technical features and unity of invention, they are not so linked as to form a single general inventive concept. Further, a prior art search also requires a literature search. It is an undue burden to search more than one invention. The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 24-32 are withdrawn from further consideration by the examiner 37CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-4, 6-21 and 39-42 drawn to an immunogenic composition comprising IL-13 and T-cell epitope with the elected species of SEQ ID NO:10 as an IL-13 element is under consideration in the instant application.

3. Applicant's claim for foreign priority under 35. U.S.C. 119(a)-(d) is acknowledged.

4. Applicant's IDS filed on 2/28/05 is acknowledged. However, Applicant is required to provide foreign patent documents for consideration.

5. Claim 6 is objected to because of the following informality: "an additionand a substitution". A proper correction is required.

6. Claim 14 is objected to under 37.CFR 1.821(d) for failing to recite the SEQ ID NO:s in the claim.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4, 6, 8, 14, 19-21 and 41 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) The phrase "the carrier protein" recited in claim 4 has no antecedent basis in the base claims 1 and 3. Only "short peptide sequence" or "T cell epitote " is recited in base claims 1 and 3.

(B) The phrase "selected from the group of" as in claims 4, 6, 8, 14, 19-21 and 41 is indefinite for using improper Markush groups. The proper Markush group recites "selected from the group consisting of"(see MPEP 2173.05 (h)).

(C) Claim 14 requires a number of substitutions at particular sequences as in item (a) and item (b) requires no mutations at specific sequences. It is noted a number of sequences "ELIEEL", "TQ", "LL" and "LF" overlaps from items (a) and (b). It is not clear how the required substitutions as in item (a) can be "unmutated" as in item (b).

(D) Claims 19 and 20 require particular substitutes from human IL-13. However, the disclosed human IL-13 (as in SEQ ID NO:1) does not contain 8T, 11R, 18V, 49E, 62K, 66M, 69G, 84H, 97K, 101L, 105K, 109E and 111R as in claims 19-20. Rather, human IL-13 as in SEQ ID NO:1 contains 7T, 10R, 17V, 48E, 61K, 65M, 68G, 83H, 96K, 100L, 104K, 108E and 110R, respectively.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

10. Claims 1-4, 6-18 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising of an IL-13 element as in SEQ ID NO:10 (Immunogen 1 as in claim 21) and an IL-13 comprises a number of directed substitutions as in claims 19-21, does not reasonably provide enablement for an immunologic composition comprising any IL-13 "element", IL-13 element having " similar conformational shape to native human IL-13", "sufficient amino acid sequence diversity", "structurally conservative substitutions" or "functionally equivalent fragment" as recited in claims 1, 14 and 42. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use of the invention commensurate in scope with these claims.

The specification disclosure does not enable one skilled in the art to practice the invention without any undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

The specification p. 5 of the instant application defines an IL-13 element as any sequence that is capable of driving an immune response that recognizes and neutralizes the biological effects of IL-13 and fragments are encompassed by the definition. Moreover, having "neutralizing" biological effect of IL-13, the IL-13 elements involve antibodies of IL-13 as well. The specification of the instant application has not provided sufficient biochemical information of any IL-13 "element", IL-13 element having " similar conformational shape to native human IL-13", "sufficient amino acid sequence diversity", "structurally conservative substitutions" or "functionally equivalent fragment" other than the IL-13 elements defined by SEQ ID NO:10 or Immunogen 1.

The specification fails to provide sufficient guidance and direction as to how the skilled artisan can make such compositions, commensurate in scope with the claimed invention. The specification fails to provide any guidance on how to make and use the immunogenic composition comprising any IL-13 "element",

IL-13 element having " similar conformational shape to native human IL-13", "sufficient amino acid sequence diversity", "structurally conservative substitutions" or "functionally equivalent fragment" thereof.

Ngo *et al* teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure will require guidance (see Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495 in particular).

In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Since the amino acid sequence of a polypeptide determined its structural property, predictability of which amino acid fragment can retain the functional capabilities of the IL-13 elements comprising polypeptide requires knowledge of, and guidance with regard to, which segments in the polypeptide's sequence contribute to its function.

Therefore, there is insufficient direction as to how to make and to use an immunogenic composition comprising any IL-13 "element", IL-13 element having " similar conformational shape to native human IL-13", "sufficient amino acid sequence diversity", "structurally conservative substitutions" or "functionally equivalent fragment which can be used as to whether such a desired effect can be achieved or predicted, as encompassed by the claims.

In view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. Claims 1-4, 6-18 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an immunogenic composition comprising of an IL-13 element as in SEQ ID NO:10 (Immunogen 1 as in claim 21) and an IL-13 comprises a number of directed substitutions as in claims 19-21; however, applicant is not in possession of an immunologic composition comprising any IL-13 "element", IL-13 element having " similar conformational shape to native human IL-13", "sufficient amino acid sequence diversity", "structurally conservative substitutions" or "functionally equivalent fragment" as recited in claims 1, 14 and 42.

The specification fails to provide what encompasses the immunogenic composition comprising any IL-13 "element", IL-13 element having " similar conformational shape to native human IL-13", "sufficient amino acid sequence diversity", "structurally conservative substitutions" or "functionally equivalent fragment" thereof other than the IL-13 elements defined by SEQ ID NO:10 or Immunogen 1.

Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-3, 6, 7, 9-18, 41 and 42 are rejected under 35 U.S.C. 102(a)(e) as being anticipated by U.S. Pat. No. 6,296,843 B1.

The '843 patent teaches an immunogenic composition comprising a human IL-13 and T-cell epitope (cytotoxin or diphteria toxin). The human IL-13 sequences at residues at 13, 66, 69, 109 and 112 (alpha helical region) are substituted with residues from non-human mammalian IL-13 sequences to result chimeric IL-13 (claims 1-12, in particular). Moreover, the '843 patent teaches that the human IL-13 and Tcell epitope are cross-linked.

The '843 patent further teaches that the Tcell epitopes are promiscuous as the cytotoxin or diphteria toxins do not differentiate but universally bind on MHC complex.

Claims 15-17 are included in this rejection because the 5 substitutions occur in the alpha helical regions.

Therefore, the reference teachings anticipate the claimed invention.

14. Claims 1-3, 6, 7, 9-18, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/51643 (IDS reference).

The '643 publication teaches an immunogenic composition comprising a human IL-13 and T-cell epitope (cytotoxin or diphteria toxin). The human IL-13 sequences at residues at 13, 66, 69, 109 and 112 (alpha helical region) are substituted with residues from non-human mammalian IL-13 sequences to result chimeric IL-13 (claims 1-30, in particular). Moreover, the '643 publciation teaches that the human IL-13 and Tcell epitope are cross-linked.

The '843 patent further teaches that the Tcell epitopes are promiscuous as the cytotoxin or diphteria toxins do not differentiate but universally bind on MHC complex.

Claims 15-17 are included in this rejection because the 5 substitutions occur in the alpha helical regions.

Therefore, the reference teachings anticipate the claimed invention.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1, 3, 4, 39 and 40 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 6,296,843 B1 or WO 99/51643 in view of U.S. Pat. No. 6,342,224B1.

The '843 patent and the '643 publication have been discussed, supra.

The '843 patent or the '643 publication do not teach cross-linking of carrier protein into the IL-13 and T-cell epitope wherein the carrier protein being Haemophilis influenza Protein D or CPC (or clyta) as in claims 4 and 39.

However, the '224 patent teaches the use of Haemophilis influenza Protein D and CPC (or clyta) in conjunction with Tcell epitope as an immunological fusion partner because having Haemophilis influenza Protein D or CPC allows higher expression of antigenic material as well as the easy purification (col. 2-4, in particular).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to fuse Haemophilis influenza Protein D and CPC as carrier protein as taught by the '224 patent in the immunogenic construct comprising IL-13 and T-cell epitope taught by the '843 patent or the '643 publication.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because cross-linking of Haemophilis influenza Protein D and CPC as taught by the '224 patent into the immunogenic composition comprising IL-13 and T-cell epitope as taught by the '843 patent or the '643 publication allows higher expression of antigenic material and easier purification of the antigenic material. The C-terminal domain of CPC is responsible for affinity to choline or choline analogues and the chromatographic purification is easier with this construct (col.2-3 overlapping paragraph, in particular).

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 6,296,843 B1 or WO 99/51643 in view of Panina-Bordignon et al (Eur. J. Immuno. 1989, 19:2237-2242).

The '843 patent and the '643 publication have been discussed, supra.

The '843 patent or the '643 publication do not teach use of P2 or P30 as in claim 8.

However, the Panina-Bordignon et al. teach the P2 and P30 have restriction specificity is already set at the level of peptide-MHC complex, they are universally immunogenic as they are recognized by all primed donors (abstract, in particular). Moreover, Panina-Bordignon et al teach the P2 and P30 are more immunogenic because their promiscuous characteristics allow diversification of immune response to avoid escape of pathgens (discussion, p. 2241-2242, in particular).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute promiscous Tcell epitope with P2 or P30 as taught by Panina-Bordignon et al. in the immunogenic construct comprising IL-13 and T-cell epitope taught by the '843 patent or the '643 publication.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because P2 or P30 promiscous Tcell epitope as taught by Panina-Bordignon et al. into the immunogenic composition comprising IL-13 and T-cell epitope as taught by the '843 patent or the '643 publication makes immunogenic composition more effective because the P2 and P30 are readily available for MHC restriction and allow diversification of immune response by avoiding escape of pathogens.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-3, 6, 7, 9-21, 41 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/526,030. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims disclose an immunogenic composition comprising IL-13 and Tcell epitopes. Both claim sets recite use of human/chimeric IL-13 and number of particular substitutions at particular amino acids with amino acid sequences from non-human mammals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 1, 3, 4, 39 and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/526,030 in view of U.S. Pat. No. 6,342,224B1.

The '030 application has been discussed, supra.

The '030 application does not teach cross-linking of carrier protein into the IL-13 and T-cell epitope wherein the carrier protein being Haemophilis influenza Protein D or CPC (or clyta) as in claims 4 and 39.

However, the '224 patent teaches the use of Haemophilis influenza Protein D and CPC (or clyta) in conjunction with Tcell epitope as an immunological fusion partner because having Haemophilis influenza Protein D or CPC allows higher expression of antigenic material as well as the easy purification (col. 2-4, in particular).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to fuse Haemophilis influenza Protein D and CPC as carrier protein as taught by the '224 patent in the immunogenic construct comprising IL-13 and T-cell epitope taught by the '030 application.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because cross-linking of Haemophilis influenza Protein D and CPC as taught by the '224 patent into the immunogenic composition comprising IL-13 and T-cell epitope as taught by the '030 application allows higher expression of antigenic material and easier purification of the antigenic material. The C-terminal domain of CPC is responsible for affinity to choline or choline analogues and the chromatographic purification is easier with this construct (col.2-3 overlapping paragraph, in particular).

This is a provisional obviousness-type double patenting rejection.

21. Claims 1-3 and 6-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/526,030 in view of Panina-Bordignon et al (Eur. J. Immuno. 1989, 19:2237-2242).

The '030 application has been discussed, supra.

The ''030 application does not teach use of P2 or P30 as in claim 8.

However, the Panina-Bordignon et al. teach the P2 and P30 have restriction specificity is already set at the level of peptide-MHC complex, they are universally immunogenic as they are recognized by all primed donors (abstract, in particular). Moreover, Panina-Bordignon et al teach the P2 and P30 are more immunogenic because their promiscuous characteristics allow diversification of immune response to avoid escape of pathgens (discussion, p. 2241-2242, in particular).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to substitute promiscous Tcell epitope with P2 or P30 as taught by Panina-Bordignon et al. in the immunogenic construct comprising IL-13 and T-cell epitope taught by the '843 patent or the '643 publication.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because P2 or P30 promiscous Tcell epitope as taught by Panina-Bordignon et al. into the immunogenic composition comprising IL-13 and T-cell epitope as taught by the '843 patent or the '643 publication makes immunogenic composition more effective because the P2 and P30 are readily available for MHC restriction and allow diversification of immune response by avoiding escape of pathogens.

This is a provisional obviousness-type double patenting rejection.

22. No claims are allowable.

23. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
October 31, 2007

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600